

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

UNKNOWN 09/830082

INTERNATIONAL APPLICATION NO.
PCT/US99/24183

INTERNATIONAL FILING DATE
15 October 1999

PRIORITY DATE CLAIMED
22 October 1998

TITLE OF INVENTION : ACCUPRESSURE TREATMENT DEVICE AND METHODS OF USE

APPLICANT(S) FOR DO/EO/US : Kramer, George H.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371 (f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:

International Search Report (7 pgs.)
PCT Request Form (5 pgs.)
International Preliminary Examination Report (13 pgs.)
Notification of Receive of Demand (1 pg.)
PCT Demand (4 pgs.)
Declaration and Power of Attorney (3 pgs.)
Small Entity Statement (1 pg.)

09/830082

17. ☒ The following fees are submitted:**BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):**

Neither international preliminary examination fee (37 CFR 1.482)
nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO
and International Search Report not prepared by the EPO or JPO **\$970.00**

International preliminary examination fee (37 CFR 1.482) not paid to
USPTO but International Search Report prepared by the EPO or JPO **\$840.00**

International preliminary examination fee (37 CFR 1.482) not paid to USPTO
but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **\$760.00**

International preliminary examination fee paid to USPTO (37 CFR 1.482)
but all claims did not satisfy provisions of PCT Article 33(1)-(4) **\$670.00**

International preliminary examination fee paid to USPTO (37 CFR 1.482)
and all claims satisfied provisions of PCT Article 33(1)-(4) **\$96.00**

ENTER APPROPRIATE BASIC FEE AMOUNT**CALCULATIONS PTO USE ONLY**

Surcharge of **\$130.00** for furnishing the oath or declaration later than 20 ☒ 30
months from the earliest claimed priority date (37 CFR 1.492(e)).

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	24 - 20 =	4	X \$9.00
Independent claims	1 - 3 =	0	X \$40.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$260.00

TOTAL OF ABOVE CALCULATIONS

Reduction of 1/2 for filing by small entity, if applicable. A Small Entity Statement must also
be filed (Note 37 CFR 1.9, 1.27, 1.28).

SUBTOTAL

Processing fee of **\$130.00** for furnishing the English translation later than 20 30
months from the earliest claimed priority date (37 CFR 1.492(f)).

TOTAL NATIONAL FEE

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be
accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **\$40.00** per property.

TOTAL FEES ENCLOSED

Amount to be:	
refunded	\$
charged	\$ 543.00

- a. ☒ Authorization to charge Deposit Account No. 19-0743 in the amount
of **\$40.00** to cover the above fee for the Assignment Recordation is
enclosed.
- b. ☒ Please charge my Deposit Account No. 19-0743 in the amount of **\$543.00** to cover the above fee for the filing
fee. A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any
overpayment to Deposit Account No. 19-0743. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive
(37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
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SIGNATURE

Robert J. Harris, Ph.D.
NAME

37,346
REGISTRATION NUMBER

S/N Unknown

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	George H. Kramer	Examiner:	Unknown
Serial No.:	Unknown	Group Art Unit:	Unknown
Filed:	Herewith	Docket:	1197.001US3
Title:	ACUPRESSURE DEVICE		

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination, please amend the above-identified application as follows.
Specific amendments to individual claims are detailed in the following marked up set of claims.
Please substitute the attached Clean Version of the claims for the previously pending claim set.

In the Claims

Please cancel claims 13-14 and 27.

Please amend claims 2, 4-11, 15-21 and 25 as follows:

2. (Amended) The device of claim 1 wherein [where in] the flexible base sheet comprises a synthetic polymeric film, synthetic polymeric fibers in a woven fabric, or natural fibers in a woven fabric.
4. (Amended) The device of claim 3 wherein [where in] the metal or metal alloy is selected from the group consisting of iron, titanium, stainless steel, nickel, copper, tin, zinc, platinum, gold, and silver.
5. (Amended) The device of claim 1 wherein [where in] the at least one bead comprises a polymeric compound, a ceramic compound, a glass compound, or a rubber compound.

PRELIMINARY AMENDMENT

Serial Number: Unknown

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6. (Amended) The device of claim 1 [as described in any one of claims 1 to 5] wherein the base sheet further comprises [comprise] a tab, suitable to wrap around a portion of the body adjacent to the selected skin surface, and adhere when the device is applied, thus providing a compression which increases the contact between the body surface and the at least one bead.
7. (Amended) The device of claim 1 [as described in any one of claims 1 to 5] wherein the selected skin surface portion of a human body is the tragus, said device further comprising a tab, suitable for adhering to the back of the tragus, and wherein the [an] orienting margin is shaped to correspond to the front of the tragus when the base sheet is placed on the selected body surface.
8. (Amended) The device [as described in] of claim 7 wherein the flexible base sheet comprises a synthetic polymeric film, synthetic polymeric fibers in a woven fabric, or natural fibers in a woven fabric; and wherein the at least one bead comprises iron, titanium, stainless steel, nickel, copper, tin, zinc, platinum, gold, or silver.
9. (Amended) The device of claim 1 [any one of claims 1 to 8] comprising two or more beads.
10. (Amended) The device of claim 1 [any one of claims 1 to 9] further comprising a release film.
11. (Amended) A kit of parts comprising the [a] device of claim 1 [as claimed in any one of claims 1 to 10], packaging material, and instructions for use in acupressure.

15. (Amended) A method for applying pressure to one or more selected points on a selected skin surface portion of a human body comprising aligning an orienting margin of the [a] device of claim 1 [as defined in any one of claims 1 to 10] with a corresponding shape on or adjacent to said skin surface portion, conforming the shape of the device to the intended site of adhesion and causing adhesion of the device, wherein said adhesion of the device results in the application of pressure to said selected points.

16. (Amended) A method for correcting an energy flow imbalance in a human comprising applying the [a] device of claim 1 [as defined in any one of claims 1 to 10] to an acupressure point on the skin of said human.

17. (Amended) A method for producing an increased sense of well-being in a human comprising applying the [a] device of claim 1 [as defined in any one of claims 1 to 10] to a selected skin surface portion of said human.

18. (Amended) A method for treating a condition selected from headache, premenstrual syndrome, stress, anxiety, muscular-skeletal pains, allergies, nausea, pain, menstrual cramps, low back pain, dental analgesia and depression, in a human comprising applying the [a] device of claim 1 [as defined in any one of claims 1 to 10] to a selected skin surface portion of said human.

19. (Amended) A method for promoting weight loss in a human comprising applying the [a] device of claim 1 [as defined in any one of claims 1 to 10] to a selected skin surface portion of said human.

20. (Amended) A method for promoting smoking cessation in a human comprising applying the [a] device of claim 1 [as defined in any one of claims 1 to 10] to a selected skin surface portion of said human.

PRELIMINARY AMENDMENT

Serial Number: Unknown

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21. (Amended) The method of claim 15 [any one of claims 15 to 20] further comprising applying external pressure one or more times to said device on the skin.

25. (Amended) The method of claim 21 [any one of claims 21 to 24] wherein the external pressure is applied by pinching said device against said skin surface portion.

Remarks

After entry of this amendment, claims 1-12 and 15-26 are pending.

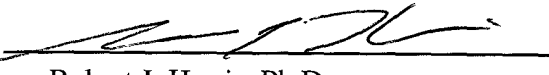
None of the amendments to the claims were made for reasons related to patentability. Thus, the Amendments do not create estoppel which would limit the claims. Accordingly, Applicant is entitled to a full range of equivalents upon issuance of the instant claims.

Respectfully submitted,

GEORGE H. KRAMER

By their Representatives,

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Date 4-20-01 By 
Robert J. Harris, Ph.D.
Reg. No. 37,346

Customer Number 21186

"Express Mail" mailing label number: EL721275702US

Date of Deposit: April 20, 2001

This paper or fee is being deposited on the date indicated above with the United States Postal Service pursuant to 37 CFR 1.10, and is addressed to the Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.

Clean Version of Pending Claims

ACUPRESSURE DEVICE
Applicant: George H. Kramer
Serial No.:

1. An acupressure device for use on a selected skin surface portion of a human body, the device comprising:
 - a thin flexible base sheet having a first side, a second side and a margin, the margin having at least a portion shaped as an orienting margin, wherein the orienting margin is shaped to correspond to a shape on or adjacent to the selected skin surface portion when the base sheet is placed on the selected body surface;
 - an adhesive layer on the first side of the base sheet suitable for attaching the base sheet to the selected skin surface portion; and
 - at least one bead on the adhesive layer suitable for positioning against the selected body surface for providing acupressure to at least a portion of the selected body surface.
2. (Amended) The device of claim 1 wherein the flexible base sheet comprises a synthetic polymeric film, synthetic polymeric fibers in a woven fabric, or natural fibers in a woven fabric.
3. The device of claim 1 wherein the at least one bead comprises a metal or metal alloy.
4. (Amended) The device of claim 3 wherein the metal or metal alloy is selected from the group consisting of iron, titanium, stainless steel, nickel, copper, tin, zinc, platinum, gold, and silver.
5. (Amended) The device of claim 1 wherein the at least one bead comprises a polymeric compound, a ceramic compound, a glass compound, or a rubber compound.

6. (Amended) The device of claim 1 wherein the base sheet further comprises a tab, suitable to wrap around a portion of the body adjacent to the selected skin surface, and adhere when the device is applied, thus providing a compression which increases the contact between the body surface and the at least one bead.

7. (Amended) The device of claim 1 wherein the selected skin surface portion of a human body is the tragus, said device further comprising a tab, suitable for adhering to the back of the tragus, and wherein the orienting margin is shaped to correspond to the front of the tragus when the base sheet is placed on the selected body surface.

8. (Amended) The device of claim 7 wherein the flexible base sheet comprises a synthetic polymeric film, synthetic polymeric fibers in a woven fabric, or natural fibers in a woven fabric; and wherein the at least one bead comprises iron, titanium, stainless steel, nickel, copper, tin, zinc, platinum, gold, or silver.

9. (Amended) The device of claim 1 comprising two or more beads.

10. (Amended) The device of claim 1 further comprising a release film.

11. (Amended) A kit of parts comprising the device of claim 1, packaging material, and instructions for use in acupressure.

12. The kit of claim 11 wherein the instructions comprise one or more pictures illustrating how to align the orienting margin with the shape on or adjacent to the selected skin surface.

15. (Amended) A method for applying pressure to one or more selected points on a selected skin surface portion of a human body comprising aligning an orienting margin of the device of claim 1 with a corresponding shape on or adjacent to said skin surface portion, conforming the shape of the device to the intended site of adhesion and causing adhesion of the device, wherein said adhesion of the device results in the application of pressure to said selected points.
16. (Amended) A method for correcting an energy flow imbalance in a human comprising applying the device of claim 1 to an acupuncture point on the skin of said human.
17. (Amended) A method for producing an increased sense of well-being in a human comprising applying the device of claim 1 to a selected skin surface portion of said human.
18. (Amended) A method for treating a condition selected from headache, premenstrual syndrome, stress, anxiety, muscular-skeletal pains, allergies, nausea, pain, menstrual cramps, low back pain, dental analgesia and depression, in a human comprising applying the device of claim 1 to a selected skin surface portion of said human.
19. (Amended) A method for promoting weight loss in a human comprising applying the device of claim 1 to a selected skin surface portion of said human.
20. (Amended) A method for promoting smoking cessation in a human comprising applying the device of claim 1 to a selected skin surface portion of said human.
21. (Amended) The method of claim 15 further comprising applying external pressure one or more times to said device on the skin.

22. The method of claim 18 further comprising applying external pressure to said device when a symptom of said condition appears or worsens.
23. The method of claim 19 further comprising applying external pressure to said device to alleviate an immediate desire to eat.
24. The method of claim 20 further comprising applying external pressure to said device to alleviate an immediate desire to smoke.
25. (Amended) The method of claim 21 wherein the external pressure is applied by pinching said device against said skin surface portion.
26. The method of claim 21 wherein the external pressure is applied multiple times over a period of hours.

ACUPRESSURE DEVICE

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Field of the Invention

The present invention relates to an acupressure device, and, in particular, to an acupressure device having a shaped peripheral margin shaped to key to specific landmarks of the human body.

Background of the Invention

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Acupressure, as with acupuncture, is a form of treatment for various conditions and maladies. Acupuncture is well known to eastern medical thought and practice, but only recently is introduced into western medicine. Acupuncture can be traced back at least 2,500 years as a form of medical treatment in China. The concept behind acupuncture is based on the premise there are patterns of energy flow through the body that are essential for proper health. Imbalance or disruption of energy flow through any of these patterns is believed to be responsible for disease. Which pattern is disrupted, and where, influences which disease state is experienced by the afflicted person.

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The energy flow patterns through the body have been mapped extensively and there are substantial numbers of points along the flow patterns where the energy flow is close to the skin surface. Using needles of various types, the acupuncturist is able to reach these points by placing the needles into the skin at these known points. The presence of the needle at that point alters the flow of energy, changing the dynamics in the energy flow. When done properly, using the proper number and position of needles, acupuncture re-aligns the energy flow to one of balance and restoration of health.

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The pattern of energy flow disruption is identifiable to the type of disease that the patient presents with. The acupuncturist determines the ailment complained of which then identifies the energy flow imbalance. The energy flow imbalance is then corrected by placing one or more needles into the appropriate points that are associated with the type of energy flow imbalance corresponding to the disease.

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The National Institutes of Health Consensus Development Statement on Acupuncture, No. 107, November 3-5, 1997, concluded that acupuncture was an effective therapy for certain medical conditions, especially those involving nausea and pain and should be integrated into standard medical practice. In particular, headaches, nausea, menstrual cramps, low back pain and dental analgesia were some of the medical conditions acupuncture was considered useful for.

The most common use for acupuncture in the U.S. is pain, with headache as the most frequent complaint in doctors' offices review of symptoms, and the most frequent reason for use of over-the-counter medications. U.S. and Chinese studies have shown acupuncture and acupressure therapy useful for pain and headache in particular. The use of acupressure therapy for headaches in the hands of the lay public could greatly enhance the treatment of headaches by a simple inexpensive technique with virtually no negative side effects.

Acupressure is a direct offshoot of acupuncture wherein one or more known points on the surface of the skin receive pressure instead of having a needle inserted. The concept remains the same, re-institute balanced energy flow as treatment of a malady caused by an imbalance in the energy flow through the body.

Acupuncture and acupressure points are at anatomically defined areas of the skin along 12 meridians, or lines of energy flow. In addition, further research has determined that there are several areas on the surface of the skin where the entire body is represented as a homunculus. Several areas incorporating a homunculus representation are the ears, hands, and soles of the feet.

Acupuncture and acupressure to portions of the ear, hand, or sole of the foot effects a corrective energy change in the part of the body represented by that part of the homunculus.

Several acupressure devices are known in the art. A few are U.S. Patent Nos. 3,866,597; 3,886,939; 3,987,787; and 4,022,189, and all issued to Boxer. The devices disclosed make use of one or more small rigid objects that are applied by the user to one or more particular points of the user's body. The devices disclosed are either square or rectangular in shape and they either have a single small object in the center or several spread randomly across the surface of

the device. Each of these devices requires that either the user or a helper have considerable knowledge and experience in determining where and how to place the objects on the user's skin. U.S. Patent No. 3,901,234 issued to Yazawa discloses a similar device to that of Boxer, but adds a medicated adhesive layer.

5 U.S. Patent No. 4,098,277 issued to Mendell discloses a custom molded, and expensive, device for use in a person's ear that bears one or more blunt protrusions of the mold surface as acupressure points. Such a device is limited to use by only the person for which the device is molded and requires skilled help in fabricating the device. Placement of the acupressure points on the device
10 is permanent. A single patient would require any number of individual custom molded devices, each device having a different pattern of acupressure points corresponding to treatment of differing maladies, in order to treat the different maladies that one person may encounter over time.

Another device is disclosed in U.S. Patent No. 4,073,296 issued to
15 McCall wherein the device is a custom molded piece, again for a single individual's ear. This device incorporates nodules inserted into the surface of the molded device to achieve the acupressure effect. Like the Mendell device, this device requires one of high skill to construct the device for proper fit and each mold can only treat the one specific malady intended.

20 What is needed is a device that is relatively inexpensive and easy enough to be applied by the user without need to involve an expert in acupressure in the process. The device will conform and mold easily to the user's skin surface. Different shapes of the device have uses outside of placement on, or about, the user's ear. For example, different shaped devices can be used at other
25 acupressure, therapy, or reflex points on the body, with each shape keyed to a particular anatomical surface shape that is readily identifiable to the user, thus providing easy accurate placement of the device.

Summary of the Invention

The invention provides an acupressure device for use on a selected skin
30 surface portion of a human body, the device comprising:

a thin flexible base sheet having a first side, a second side and a margin, the margin having at least a portion shaped as an orienting margin, wherein the

orienting margin is shaped to correspond to a shape on or adjacent to the selected skin surface portion when the base sheet is placed on the selected body surface;

an adhesive layer on the first side of the base sheet suitable for attaching the base sheet to the selected skin surface portion; and

5 at least one bead on the adhesive layer suitable for positioning against the selected body surface for providing acupressure to at least a portion of the selected body surface. An acupressure device of the invention can conveniently further comprise one or more release films, suitable to cover the adhesive layer and bead(s) and suitable to be removed prior to application of the device.

10 An object of the present invention is to provide a device that may be applied by any user with out any need for formal training in acupressure treatment or anatomy. Such a device anticipates construction with materials that are medically approved and hypoallergenic.

Another object of the present invention is to provide a device that is
15 capable of adapting to a number of different treatments. This is accomplished by using any number of beads, in any number of different patterns, appropriate for any number of individual maladies and pains. The various different numbers of patterns are keyed to the corresponding orienting margins, which are then alignable to the appropriate anatomical landmark. This is to ensure that the
20 proper treatment is applied to the proper skin area corresponding to the anatomical landmark.

These and other objects of the present invention and many of the attendant advantages of the present invention will be readily appreciated as the same become better understood by reference to the following detailed
25 description when considered in connection with the accompanying drawings.

The invention also provides a kit of parts comprising a device as described herein, packaging material, and instructions for use in acupressure. The instructions may preferably comprise one or more pictures illustrating how to align the orienting margin with the shape on or adjacent to the selected skin
30 surface.

The invention also provides the use of a device as described herein in acupressure.

The invention also provides the use of a device as described herein for application of pressure to an acupressure, therapy, or reflex point on the skin of a human.

The invention also provides a method for applying pressure to one or
5 more selected points on a selected skin surface portion of a human body comprising aligning an orienting margin of a device as described herein with a corresponding shape on or adjacent to said skin surface portion, conforming the shape of the device to the intended site of adhesion and causing adhesion of the device, wherein said adhesion of the device results in the application of pressure
10 to said selected points.

The invention also provides a method for correcting an energy flow imbalance in a human comprising applying a device as described herein to an acupressure point on the skin of said human.

The invention also provides a method for producing an increased sense of
15 well-being in a human comprising applying a device as described herein to a selected skin surface portion of said human.

The invention also provides a method for treating a condition selected from headache, premenstrual syndrome, stress, anxiety, muscular-skeletal pain, allergies, and depression, in a human, comprising applying a device as described
20 herein to a selected skin surface portion of said human.

The invention also provides a method for promoting weight loss (or alleviating a desire to eat) in a human comprising applying a device as described herein to a selected skin surface portion of said human.

The invention also provides a method for promoting smoking cessation
25 (or alleviating a desire to smoke) in a human comprising applying a device as described herein to a selected skin surface portion of said human.

The methods of the invention described herein may further comprise applying external pressure one or more times to the applied device. Such external pressure may be applied when an undesirable symptom of a condition
30 to be treated appears or worsens. The external pressure may also be applied to alleviate an immediate desire to eat or smoke. External pressure can conveniently be applied, for example, by pinching a device of the invention against the skin surface to which it is attached. Additionally, external pressure

can conveniently be applied multiple times over a period of time (e.g. hours or days).

Brief Description of the Drawings

Figure 1 is a bottom plan view of an embodiment of the present invention;

Figure 2 is a side elevational view of the embodiment depicted in Figure 1;

Figure 3 is a top plan view of the embodiment depicted in Figure 1 showing the relationship of the device to a specific anatomic landmark;

Figure 4 is a top plan view of an alternative embodiment of the present invention shown in relationship to a specific anatomic landmark;

Figure 5 is a side elevational view of the embodiment depicted in Figure 4 shown in position in relationship to a specific anatomic landmark;

Figure 6 is a bottom plan view of an additional alternative embodiment of the present invention;

Figure 7 is a top plan view of the embodiment depicted in Figure 6 shown in relationship to a specific anatomic landmark;

Figure 8 is a bottom plan view of another additional alternative embodiment of the present invention;

Figure 9 is a partial plan view of the embodiment depicted in Figure 8 shown wrapping over a specific anatomic landmark;

Figure 10 is a side elevational view of the embodiment of Figure 8 shown in relationship to a specific anatomic landmark;

Figure 11, for reference, depicts a ventral view of a homunculus representation found on the palmar surface of a human hand;

Figure 12, for reference, depicts a dorsal view of a homunculus representation found on the dorsal surface of a human hand;

Figure 13 depicts a top plan view of a further additional embodiment of the present invention aligned with a specific anatomic relationship as shown by the arrows as to where the device is to be placed on the skin;

Figure 14 depicts a top plan view of an another further additional embodiment of the present invention aligned with a specific anatomic

relationship as shown by the arrows as to where the device is to be placed on the skin;

Figure 15 depicts a top plan view of yet another further additional embodiment of the present invention aligned with a specific anatomic relationship as shown by the arrows as to where the device is to be placed on the skin; and

Figure 16 depicts a top plan view of yet another further additional embodiment of the present invention aligned with a specific anatomic relationship as shown by the arrows as to where the device is to be placed on the skin.

Figure 17 depicts a device which is further embodiment of the invention and illustrates how the device can be applied to tragus.

Detailed Description of the Invention

In reference to the various Figures, wherein like reference numbers refer to like components throughout the various Figures, there is disclosed an embodiment of the present invention is depicted in Figures 1 and 2 as an acupressure patch 20 comprising a base sheet 22 and at least one bead 24. Base sheet 22 includes an adhesive layer 26, an opposite outer surface 28 and a peripheral margin 30. Peripheral margin 30 includes an orienting margin 32 that is at least a portion of peripheral margin 30. As depicted in Figure 2a and 2b, a release film 29 can be placed over adhesive layer 26 at the time of manufacture. For example, the release layer may cover the at least one bead 24 (figure 2a) or may comprise perforations allowing the at least one bead 24 to project through the release layer (Figure 2b). The purpose of a release film is to provide for convenient packaging and to prevent premature, inadvertent or undesired application of acupressure patch 20. The types and uses of release films are well known in the art.

Base sheet 22 may be manufactured from a number of different materials ranging from a cloth to a film. Various cloths useful as a base sheet include weaves made from synthetic or natural fibers, or a blend of both. Useful fibers include cotton, Dacron, polyester, and nylon. Alternatively, the base sheet may be a film made from natural or synthetic polymers and copolymers including cellulose, cellulose acetate, polyurethane, polyvinyl chloride, polyester, polypropylene, polyethylene, polytetrafluoroethylene, and various silicones and

siloxane polymers. The film may be also be a foamed plastic. Preferably, the material used for base sheet 22 is of medical grade material desirable for its biocompatibility and is hypoallergenic. Specifically, the flexible base sheet can conveniently comprise a synthetic polymeric film, synthetic polymeric fibers in a woven fabric, or natural fibers in a woven fabric.

The at least one bead 24 may include any number of beads from one to greater than ten, or even twenty beads arranged in a pattern intended for any number of possible treatment patterns, examples of which are to be explained below. Spacing of the beads is also dependent on the intended therapy and the site of on the skin the acupressure patch is to be placed. The size of the beads may vary in diameter from less than about 0.5 mm to greater than about 2 mm. Specifically, the device of the invention can conveniently comprise two or more beads, three or more beads, four or more beads, or five or more beads.

The beads may be manufactured from a number of different materials including metals, metal alloys, various ceramics and glasses, hard rubbers, and hard polymers. Useful metals include iron, titanium, stainless steel, nickel, copper, tin, zinc, platinum, gold and silver, and the various alloys attainable with these metals. A choice of metal or metal alloy may also depend on whether it is desired to include magnetic therapy using a magnetized metal or alloy with the use of the acupressure patch.

Adhesive layer 26 may be constructed from various adhesives in the form of pressure sensitive adhesives that are well known to the art. Choice of an appropriate adhesive is guided by a desire to provide a medical grade, biocompatible, and hypoallergenic adhesive with good adhesive quality.

Adhesive layer 26 is also useful in adhering at least one bead 24 to base sheet 22.

Peripheral margin 30 includes at least a portion of peripheral margin 30 as orienting margin 32. The present invention contemplates the use various surface anatomic landmarks adjacent to known meridian points and homunculus representations to shape orienting margin to conform to the various surface anatomic landmarks of interest. By way of example, it is known that a person's head is represented on a portion of the person's pinna very near the anatomic landmark identified as the antitragus. The points of interest to the head correspond to therapy points used in acupressure to promote relief from

headache occurring in those areas of the head so represented. This pattern of representation and the pattern's spatial relationship to the antitragus is uniform from one person to the next. Therefore, orienting margin 32 may be shaped to contour the base of the antitragus, and at least one bead 24 may be positioned on base sheet 22 relative to orienting margin 32 to correspond to at least one therapy point in the vicinity of the antitragus (AT in the various Figures). Just such an example using six known therapy points is depicted in Figure 4.

As shown in Figure 4, on the outer surface of a person's pinna near the antitragus and just superior to the lobe of the pinna there are represented at least six ipsilateral areas of the corresponding skull. These six areas are frontal skull F, temporal skull T, occipital skull O, vertex of skull V, frontal sinus FS, and master sensorial MS. Note the spatial relationship of these six areas to the antitragus. As shown in Figure 3, orienting margin 32 is shaped to conform to the outline of the base of the antitragus and six beads 24 are positioned across the surface of base sheet 22 to correspond to the six areas of the skull. When the user positions orienting margin 32 to conform to the base of the antitragus, the six beads 24 will then align with the six areas of the skull represented there on the surface of the pinna. Thus, even a user untrained in the art of acupressure successfully accomplishes acupressure therapy.

Figure 4 depicts a variation of the embodiment of the present invention wherein orienting margin 32 extends an accessory lobe 34 to an adjacent therapy point. In this example, accessory lobe 34 is extended to the therapy point on the inner surface of the pinna representing area subcortex SC by folding accessory lobe 34 over the rim the anithelix of the pinna to reach SC. Figure 5 shows a side elevational view depicting how this positioning is accomplished.

A majority of the surface of a person's pinna represents the body in the form of a homunculus. As noted above, various areas of a person's ipsilateral skull area represented by therapy points proximate the antitragus. Figure 6 discloses an acupressure patch 40 having an orienting margin 42 and at least one bead 44. In Figure 7, there is shown the representative points of the body for the uterus point UP and the chainman SM which are found near the inner margin of the helix. Acupressure patch 40 is positioned with orienting margin 42 adjacent

the inner margin of the helix to position beads 44 over the therapy points UP and SM.

Another example is depicted in Figures 8-10 disclosing an acupressure patch 50 having an orienting margin 52 in the shape of a wasp waste and at least one bead 54. Represented on the surface of a person's pinna are two antidepressant areas AD1 and AD2. These two areas are opposite each other over the rim of the antihelix proximate the point where the antihelix meets the edge of the antitragus. Orienting margin 52 fits within the hollow found at the junction between the antihelix and antitragus thus positioning acupressure patch 50 and its associated beads 54 over therapy points 1 and 2.

Also contemplated by the present invention, as depicted in Figure 2, is the addition of a layer of medicament 29 or a medicament that can be mixed or blended into the base sheet material. The layer may be to either surface of the base sheet depending on the material used in the base sheet and film versus weave construction. The medicament is then available to the wearer of the device, for absorption through their skin, as an additional adjunct to the acupressure effects provided by the at least one bead. Examples of useful medicaments include camphor, tiger balm, wintergreen or other pharmacological agents for transdermal or topical use.

In a preferred device of the invention the selected skin surface portion of a human body is the tragus, and the device comprises a tab suitable for adhering to the back of the tragus, and an orienting margin shaped to correspond to the front of the tragus when the base sheet is placed on the surface of the ear (see Figure 17). Such a device is particularly useful for promoting weight loss or smoking cessation.

The previous description is exemplary of a few of the many embodiments contemplated by the present invention for use on or about the ear (E). The use of an orienting margin can be extended to any surface area of the human body. For example, as shown diagrammatically in Figures 11 and 12, the body is represented in homunculus form on the surface of the hand. In Figure 11, on the palmar surface one notes the representation of the ventral surface and internal organs of the human. In Figure 12, the dorsal aspect of the body is represented on the extensor surface of the hand. These maps are uniform from one person to

the next. The present invention, using the orienting margin concept, provides for any number of acupressure patches that can be placed reproducibly, by anyone regardless of level of skill in the art of acupressure.

Figures 13-16 depicted representative examples of the various types of embodiments contemplated by the present invention for exploiting the known acupressure and acupuncture sites on the human body. Figure 13 depicts an acupressure patch 60 having an orienting margin 62,62' and at least one bead 64 shown in phantom as being on the other side of acupressure patch 60. Such an acupressure patch is useful for placing beads in a pattern for treating anterior portions of the head, face, neck and upper chest. The pattern of beads used is variable, depending on the area of the body desired to be treated by acupressure to the equivalent homunculus area, and is not a limiting factor in the present invention. Orienting margin 62,62' is used to align acupressure patch 60 to the user's finger. In Figure 13, orienting margin 62,62' is used to align acupressure patch 60 so orienting margin 62,62' is between the user's metacarpophalangeal joint MCPJ and the proximal interphalangeal joint PIPJ. The several arrows show how the device is moved into place relative to the MCPJ, PIPJ and the distal interphalangeal joint DIPJ. The long axis of acupressure patch 60 is aligned along the midline of the finger.

Figure 14 depicts an acupressure patch 70 as an embodiment of the present invention useful for treating disorders associated with the back of the head and spine. Acupressure patch 70 includes an orienting margin 72,72' and at least one bead 74. In this embodiment, orienting margin 72,72' is aligned with the plane of the DIPJ on the extensor surface of the user's finger and the long axis of acupressure patch 70 is aligned along the midline of the finger.

Figure 15 depicts another variation of an embodiment of the present invention as an acupressure patch 80 having an orienting margin 82,82' and at least one bead 84. Orienting margin 82,82' is aligned between two joints, in this example between the PIPJ and the DIPJ. The long axis is again aligned with the midline of the finger.

Figure 16 depicts an acupressure patch 90 having an orienting margin 92,92' and at least one bead 94. This embodiment depicts one use of an orienting margin for obtaining alignment of an acupressure patch to the contours of a

user's palm. Orienting margin 92,92' is used to align acupressure patch 90 along the midline of a digit, to the MCPJ of that digit, and to the web areas between the digit and the two digits to either side.

Figure 17 depicts a human ear and a tragus 102. A device of the invention 104 comprising one or more beads 106, an orienting margin 108, 108' that is suitable to orient the beads to selected therapy points on the tragus, and a tab 110 that is suitable for adhering to the back of the tragus. The orienting margin is aligned on the tragus and the device applied to the ear with the tab toward the interior of the ear 112. The tab is folded around to the back of the tragus to complete placement of the device 114.

According to the invention, the base sheet may comprise a tab, suitable to wrap around a portion of the body adjacent to the selected skin surface, and adhere when the device is applied, thus providing a compression which increases the contact between the body surface and the at least one bead. For example, a device comprising such a tab is illustrated in Figure 17.

There are other areas, including homunculus equivalent areas, elsewhere on the surface of a body. In particular, there are twelve meridians and the homunculi of the feet and nose may also be approached for treatment with a device of the present invention. The number of possible embodiments is extensive and overly burdensome to depict and describe each and every one. The principles of the present invention have been presented and depicted herein.

The foregoing description is considered as illustrative only of the principles of the invention, and since numerous modifications and changes will readily occur to those skilled in the art, it is not the inventor's desire to limit the invention to the exact construction and operation shown and described herein. Accordingly, all suitable modifications and equivalents may be resorted to, falling within the scope of the present invention.

What is claimed is:

1. An acupressure device for use on a selected skin surface portion of a human body, the device comprising:

a thin flexible base sheet having a first side, a second side and a margin, the margin having at least a portion shaped as an orienting margin, wherein the orienting margin is shaped to correspond to a shape on or adjacent to the selected skin surface portion when the base sheet is placed on the selected body surface;

an adhesive layer on the first side of the base sheet suitable for attaching the base sheet to the selected skin surface portion; and

at least one bead on the adhesive layer suitable for positioning against the selected body surface for providing acupressure to at least a portion of the selected body surface.

2. The device of claim 1 where in the flexible base sheet comprises a synthetic polymeric film, synthetic polymeric fibers in a woven fabric, or natural fibers in a woven fabric.

3. The device of claim 1 wherein the at least one bead comprises a metal or metal alloy.

4. The device of claim 3 where in the metal or metal alloy is selected from the group consisting of iron, titanium, stainless steel, nickel, copper, tin, zinc, platinum, gold, and silver.

5. The device of claim 1 where in the at least one bead comprises a polymeric compound, a ceramic compound, a glass compound, or a rubber compound.

6. The device of as described in any one of claims 1 to 5 wherein the base sheet comprise a tab, suitable to wrap around a portion of the body adjacent to the selected skin surface, and adhere when the devise is applied, thus providing a

compression which increases the contact between the body surface and the at least one bead.

7. The device as described in any one of claims 1 to 5 wherein the selected skin surface portion of a human body is the tragus, said device comprising a tab, suitable for adhering to the back of the tragus, and an orienting margin shaped to correspond to the front of the tragus when the base sheet is placed on the selected body surface.

8. The device as described in claim 7 wherein the flexible base sheet comprises a synthetic polymeric film, synthetic polymeric fibers in a woven fabric, or natural fibers in a woven fabric; and wherein the at least one bead comprises iron, titanium, stainless steel, nickel, copper, tin, zinc, platinum, gold, or silver.

9. The device of any one of claims 1 to 8 comprising two or more beads.

10. The device of any one of claims 1 to 9 further comprising a release film.

11. A kit of parts comprising a device as claimed in any one of claims 1 to 10, packaging material, and instructions for use in acupressure.

12. The kit of claim 11 wherein the instructions comprise one or more pictures illustrating how to align the orienting margin with the shape on or adjacent to the selected skin surface.

13. Use of a device as claimed in any one of claims 1 to 10 in acupressure

14. Use of a device as claimed in any one of claims 1 to 10 for application of pressure to an acupressure, therapy or reflex point on the skin of a human.

15. A method for applying pressure to one or more selected points on a selected skin surface portion of a human body comprising aligning an orienting

margin of a device as defined in any one of claims 1 to 10 with a corresponding shape on or adjacent to said skin surface portion, conforming the shape of the device to the intended site of adhesion and causing adhesion of the device, wherein said adhesion of the device results in the application of pressure to said selected points.

16. A method for correcting an energy flow imbalance in a human comprising applying a device as defined in any one of claims 1 to 10 to an acupressure point on the skin of said human.

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17. A method for producing an increased sense of well-being in a human comprising applying a device as defined in any one of claims 1 to 10 to a selected skin surface portion of said human.

18. A method for treating a condition selected from headache, premenstrual syndrome, stress, anxiety, muscular-skeletal pains, allergies, and depression, in a human comprising applying a device as defined in any one of claims 1 to 10 to a selected skin surface portion of said human.

19. A method for promoting weight loss in a human comprising applying a device as defined in any one of claims 1 to 10 to a selected skin surface portion of said human.

20. A method for promoting smoking cessation in a human comprising applying a device as defined in any one of claims 1 to 10 to a selected skin surface portion of said human.

21. The method of any one of claims 15 to 20 further comprising applying external pressure one or more times to said device on the skin.

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22. The method of claim 18 further comprising applying external pressure to said device when a symptom of said condition appears or worsens.

23. The method of claim 19 further comprising applying external pressure to said device to alleviate an immediate desire to eat.
24. The method of claim 20 further comprising applying external pressure to
5 said device to alleviate an immediate desire to smoke.
25. The method of any one of claims 21 to 24 wherein the external pressure is applied by pinching said device against said skin surface portion.
- 10 26. The method of claim 21 wherein the external pressure is applied multiple times over a period of hours.
27. An acupressure device as claimed in claim 1, substantially as described herein with reference to the drawings.

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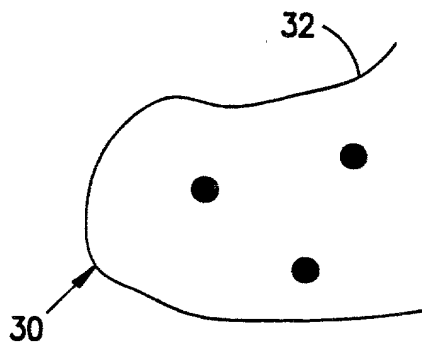


FIG. 1

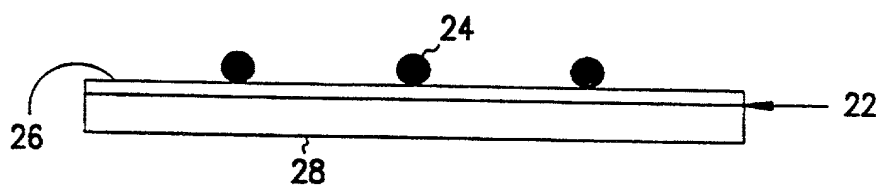


FIG. 2

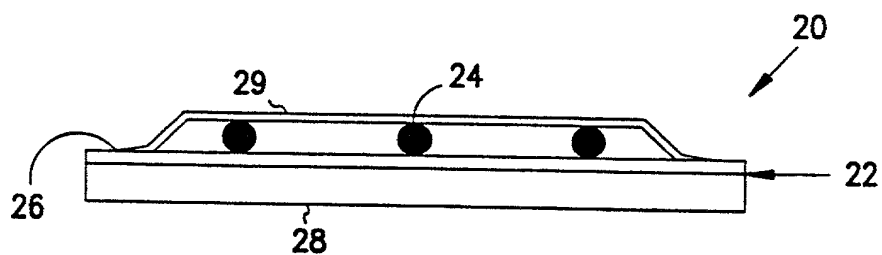


FIG. 2a

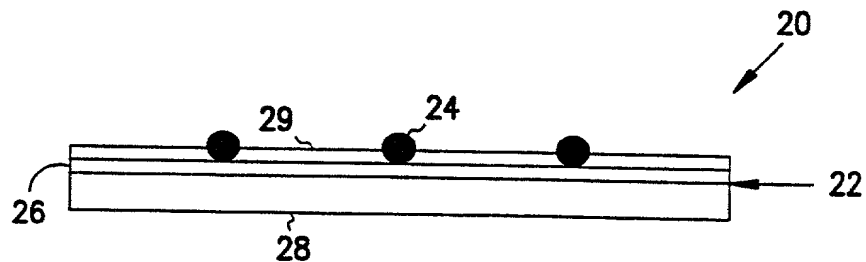


FIG. 2b

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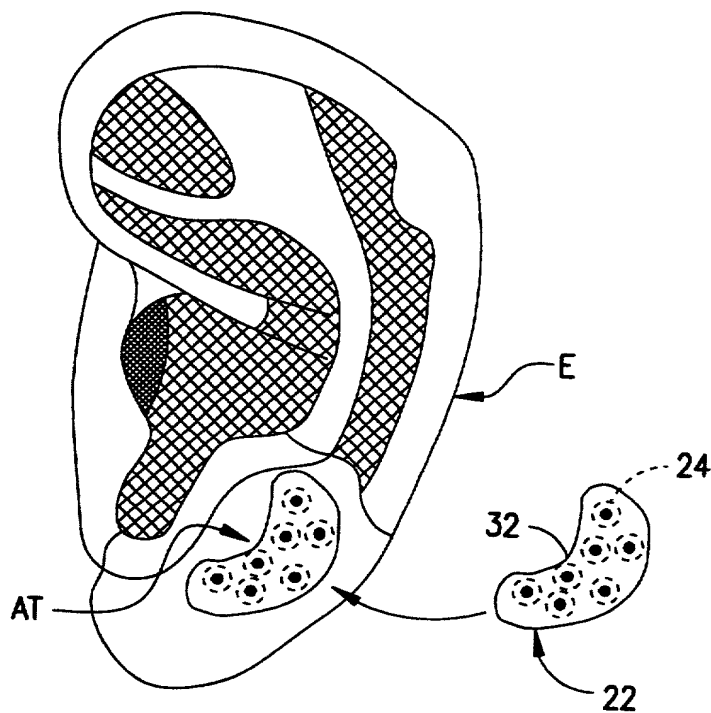


FIG. 3

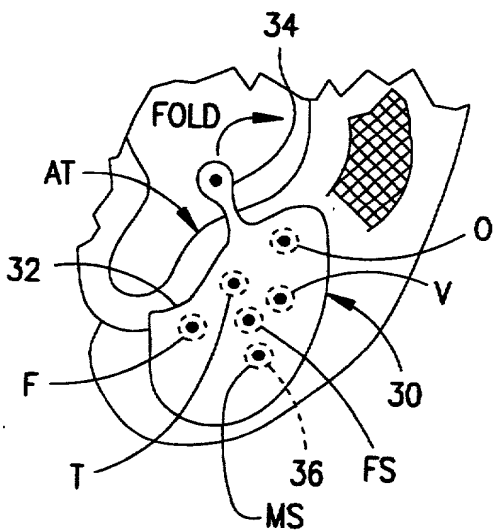


FIG. 4

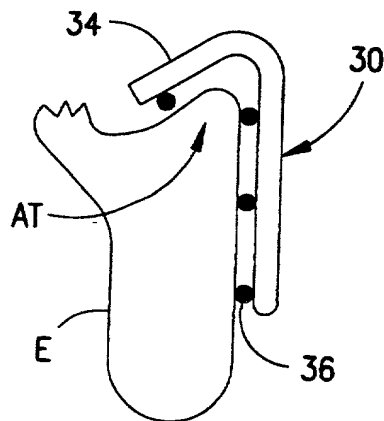


FIG. 5

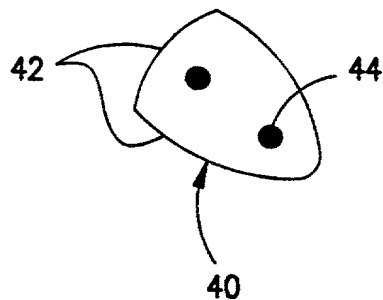


FIG. 6

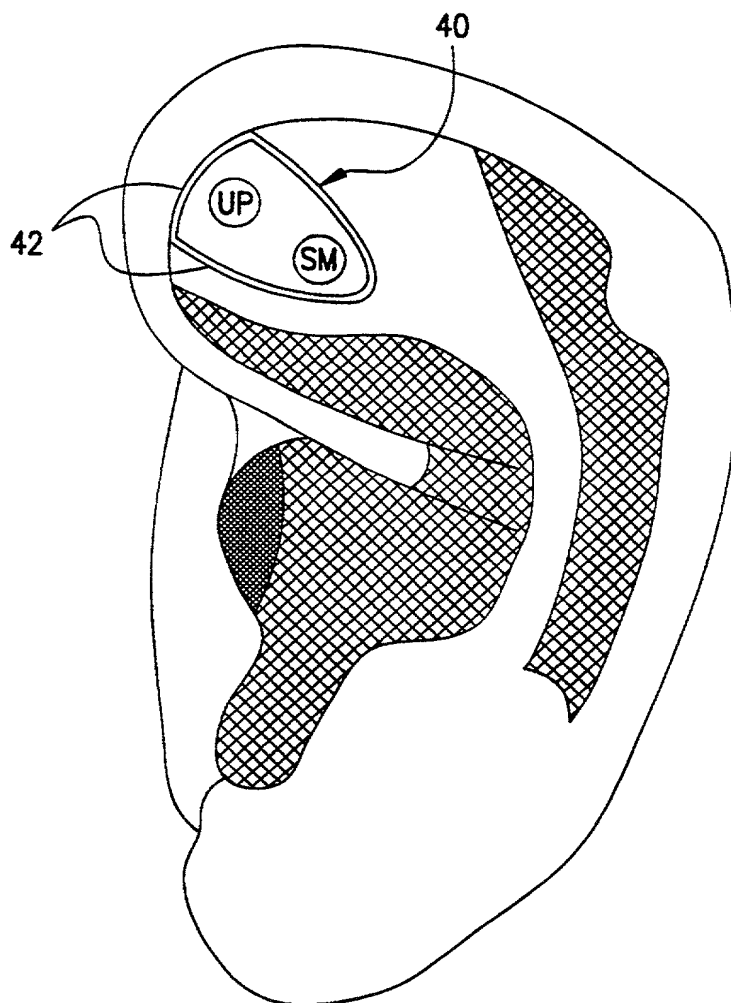


FIG. 7

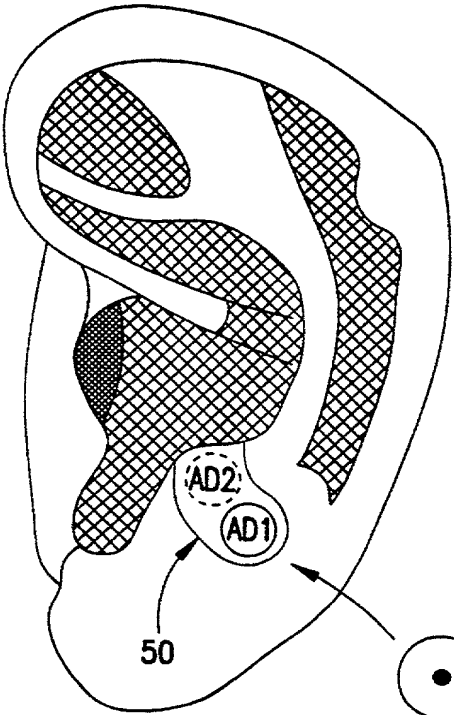


FIG. 9

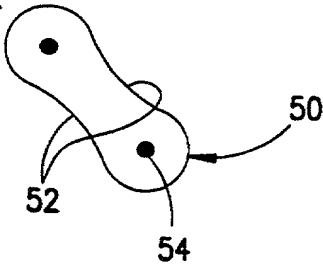


FIG. 8

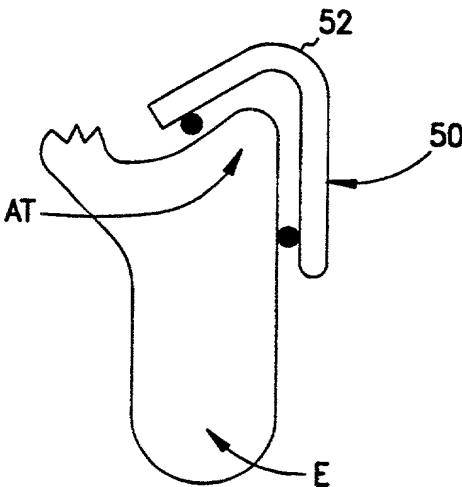


FIG. 10

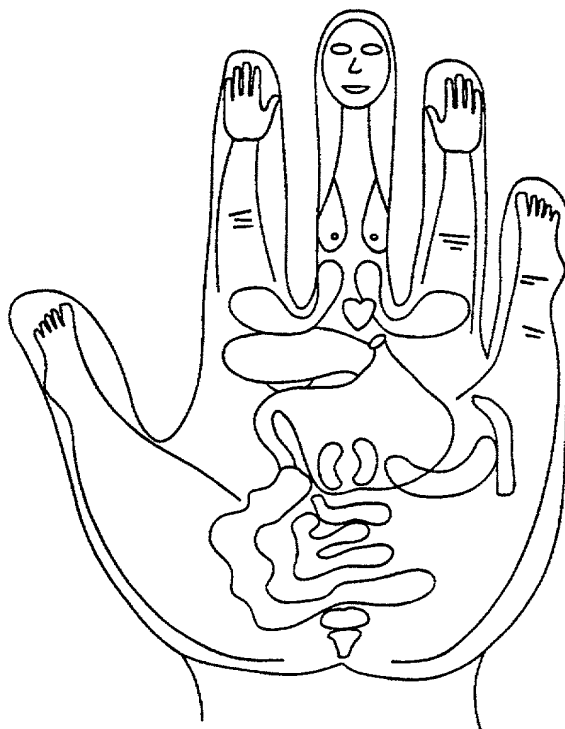


FIG. 11

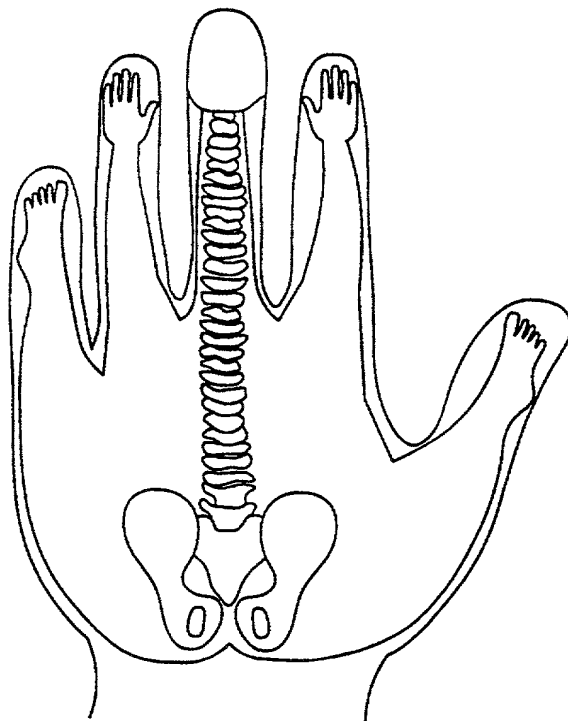


FIG. 12

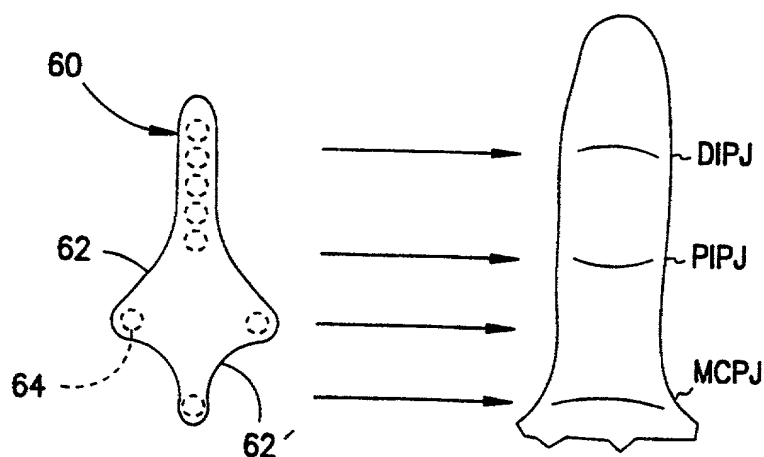


FIG. 13

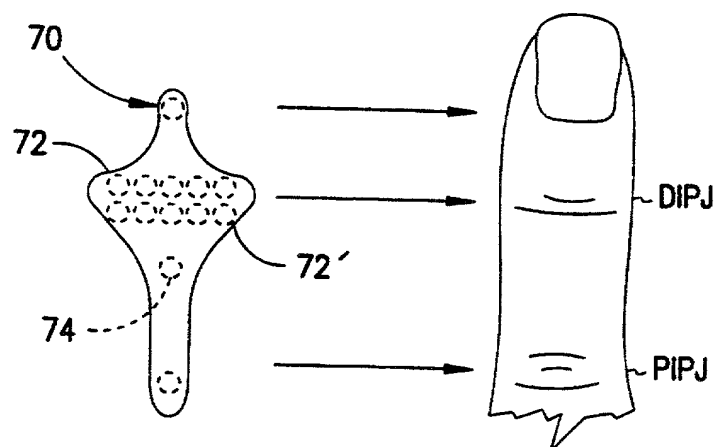


FIG. 14

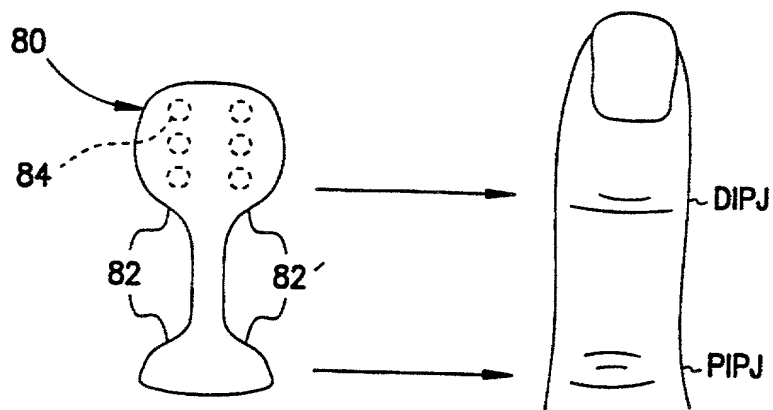


FIG. 15

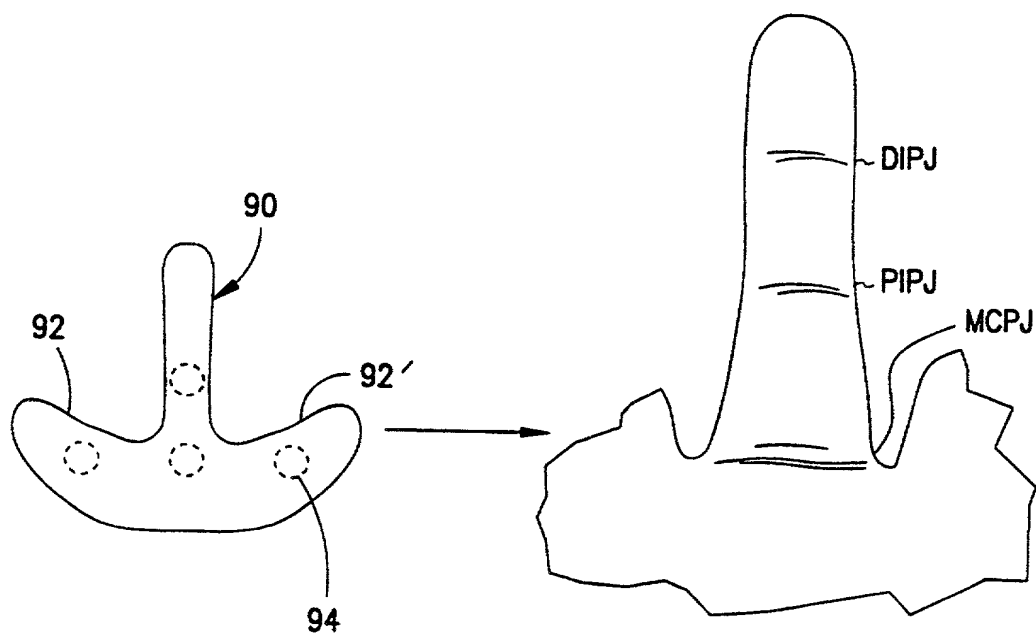


FIG. 16

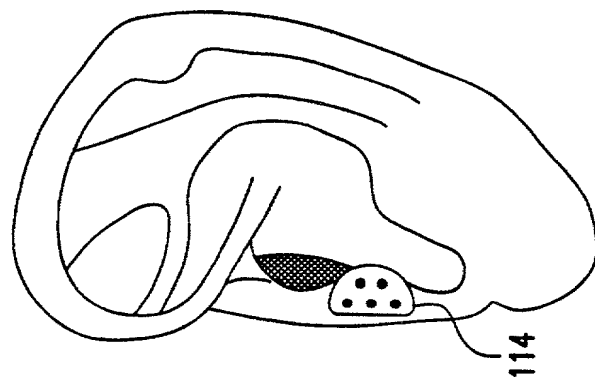


FIG. 17c

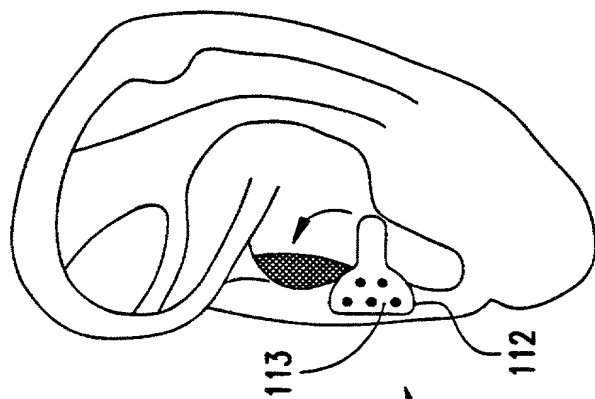


FIG. 17b

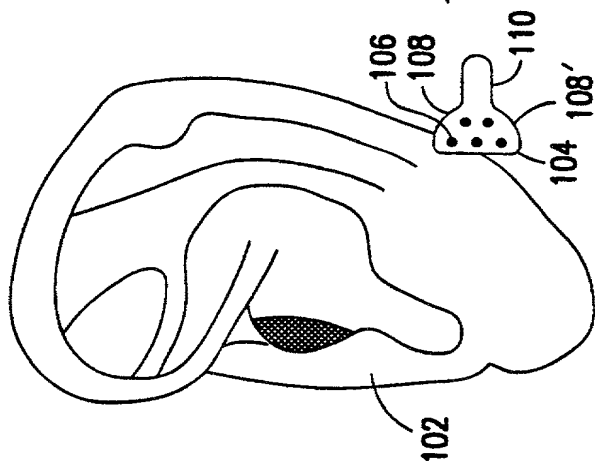


FIG. 17a

Attorney Docket No. 1197.001US3

SCHWEGMAN ■ LUNDBERG ■ WOESSNER ■ KLUTH

United States Patent Application
COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor of the subject matter which is claimed and for which patent is sought on the invention entitled: ACUPRESSURE DEVICE. ✓

the specification of which was filed on October 15, 1999 as application serial no. not assigned.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 C.F.R. § 1.56 (attached hereto). I also acknowledge my duty to disclose all information known to be material to patentability which became available between a filing date of a prior application and the national or PCT international filing date in the event this is a Continuation-In-Part application in accordance with 37 C.F.R. 1.63(e).

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or 365(b) of any foreign application(s) or patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application or patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

No such claim for priority is being made at this time.

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

No such claim for priority is being made at this time.

I hereby claim the benefit under 35 U.S.C. § 120 or 365(c) of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. § 1.56(a) which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Application Number
PCT/US99/24183 ✓

Filing Date
October 15, 1999 ✓

Status
Complete

Money Docket No.: 1197.001US3
Int. No. not assigned
Reg. Date: October 15, 1999

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact business in the Patent and Trademark Office connected herewith:

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ora, Samuel	Reg. No. 42,267	Harris, Robert J.	Reg. No. 37,346	Padys, Danny J.	Reg. No. 35,635
okman, Marvin L.	Reg. No. 38,377	Hill, Stanley K.	Reg. No. 37,548	Parker, J. Kevin	Reg. No. 33,024
anchi, Timothy E.	Reg. No. 39,610	Jackson Huachsch, Katharine A.	Reg. No. 47,670	Perdok, Monique M.	Reg. No. 42,989
liam, Richard E.	Reg. No. 32,836	Jurkovich, Paul J.	Reg. No. 44,813	Peterson, David C.	Reg. No. 47,857
ack, David W.	Reg. No. 42,331	Kalis, Janal M.	Reg. No. 37,650	Prout, William F.	Reg. No. 33,995
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annan, Thomas F.	Reg. No. 35,075	Kluth, Daniel J.	Reg. No. 32,146	Schwegman, Michael L.	Reg. No. 25,816
okas, Edward J., III	Reg. No. 40,925	Levy, Rodney L.	Reg. No. 41,136	Scott, John C.	Reg. No. 38,613
adwick, Robin A.	Reg. No. 36,477	Lemaire, Charles A.	Reg. No. 36,198	Smith, Michael G.	Reg. No. 45,368
ark, Barbara J.	Reg. No. 38,107	LeMoine, Dana B.	Reg. No. 40,062	Speier, Gary J.	Reg. No. 45,458
ise, Timothy B.	Reg. No. 40,957	Lundberg, Steven W.	Reg. No. 30,568	Staffley, Charles E.	Reg. No. 25,179
uhl, John M.	Reg. No. 44,639	Maki, Peter C.	Reg. No. 42,832	Stondal, Leif T.	Reg. No. 46,251
ake, Eduardo E.	Reg. No. 40,594	Malen, Peter L.	Reg. No. 44,894	Tarty, Kathleen R.	Reg. No. 31,884
alverson, Janet E.	Reg. No. 39,665	Mares, Robert E.	Reg. No. 35,271	Tong, Viet V.	Reg. No. 45,416
urdenbacher, Paul J.	Reg. No. 42,546	McCrackin, Ann M.	Reg. No. 42,858	Vilomina, Ann S.	Reg. No. 37,748
street, Bradley A.	Reg. No. 30,837	Moore, Charles L., Jr.	Reg. No. 33,742	Vogel, Peter J.	Reg. No. 41,363
amoa, Owen J.	Reg. No. 36,143	Nama, Kashi	Reg. No. 44,245	Woessner, Warren D.	Reg. No. 30,440
ortych, Joseph E.	Reg. No. 41,791	Nelson, Albin J.	Reg. No. 28,650		

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Please direct all correspondence in this case to Schwegman, Lundberg, Woessner & Kluth, P.A. at the address indicated below:
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Telephone No. (612)373-6900

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Minnetonka, MN 55345
Signature: George H. Kramer Date: 4/18/2001

Priority Document No.: 1197.001US3
Pat. No. not assigned
Filing Date: October 15, 1999

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1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled, withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled, withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.